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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ART UNIT	PAPER NUMBER
1642	4

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/599,087	LUETHY ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2002 and 28 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on September 25, 2002 (Paper No. 17) has been entered.

2. The amendment filed September 25, 2002 in Paper No. 18 is acknowledged and has been entered. Claims 1-3 have been amended.

3. The declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed September 25, 2002 as part of Paper No. 18 is acknowledged and has been entered.

4. The amendment filed January 28, 2003 in Paper No. 20 is acknowledged and has been entered. Claims 9, 12-45, and 49-59 have been canceled. Claim 3 has been amended.

5. Claims 1-8 are pending in the application and claims 1, 2, and 3-8, in part, are currently under continued prosecution.

Election/Restrictions

6. Newly amended claims 3-8 are directed, in part, to inventions that are independent or distinct from the invention originally claimed for the following reasons:

Claim 3 is drawn to a nucleic acid molecule comprising the nucleotide sequence encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 22, or a nucleotide sequence complementary to said nucleotide sequence encoding

SEQ ID NO: 22. Therefore, claim 3 encompasses the elected invention, i.e., a nucleic acid molecule comprising the polynucleotide sequence set forth in SEQ ID NO: 4 encoding the amino acid sequence set forth in SEQ ID NO: 5. However, claim 3 also encompasses the non-elected invention of group 1, as identified in the Office action mailed April 11, 2001 (Paper No. 7). Additionally, claim 3 encompasses a multitude of other distinct inventions, or distinct nucleic acid molecules comprising polynucleotide sequences encoding polypeptides comprising amino acid sequences that differ from the amino acid sequence encoded by the elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 3-8, to the extent that the claims are drawn to non-elected inventions, are withdrawn from consideration as being directed to a non-elected invention. In other words, claim 3 is only considered herein to the extent that the claim is drawn to a nucleic acid molecule comprising the polynucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 5. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to the Declaration under 37 CFR § 1.131

7. The declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed September 25, 2002 as part of Paper No. 18 is sufficient to overcome the FAPESP/LICR Human Cancer Genome Project (GENBANK Accession No. AW351839) reference.

Although the declaration does not provide an explicit showing that establishes the conception, or a reduction to practice of an isolated nucleic acid molecule comprising the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1449, it is presumed that the DNA insert to which claims 1 and 2 refer is the same as a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide as set forth in SEQ ID NO: 5. Because the declaration provides a showing sufficient to antedate the FAPESP/LICR Human Cancer Genome Project (GENBANK Accession No. AW351839, 01 February 2000) reference, which includes evidence of conception, and reduction to

practice of a nucleic acid molecule having the polynucleotide sequence set forth in SEQ ID NO: 4 encoding the amino acid sequence of SEQ ID NO: 5, the declaration is also deemed to provide a suggestion of the conception, if not a reduction to practice of an isolated nucleic acid molecule comprising the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1449.

Additionally, for clarity of record, according to the disclosure, a nucleic acid molecule encoding the human SECS-1 polypeptide, i.e., SEQ ID NO: 5, was subcloned into a vector designated p7T73D and the resultant clone was deposited on April 25, 2000 as Deposit No. PTA-1755 (page 84, lines 15-19). As the DNA insert of claims 1 and 2 is defined at page 2, lines 26-29, to be a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4, it is clear that the polynucleotide sequence of the DNA insert differs from SEQ ID NO: 4, but nowhere is the polynucleotide sequence of the DNA insert actually described. Even so, the FAPESP/LICR Human Cancer Genome Project (GENBANK Accession No. AW351839) reference discloses an isolated nucleic acid molecule having a polynucleotide sequence that is identical to SEQ ID NO: 4, and the reference does not therefore anticipate the present claim to an isolated nucleic acid molecule comprising the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1449. Accordingly, even if the declaration were deemed insufficient to establish the conception, or a reduction to practice of an isolated nucleic acid molecule comprising the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1449 by Applicants before the publication date of the FAPESP/LICR Human Cancer Genome Project (GENBANK Accession No. AW351839), the reference does not anticipate a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4.

Grounds of Objection and Rejection Withdrawn

8. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed June 4, 2002 (Paper No. 15) have been withdrawn.

For clarity of record, the grounds of rejection of claims 1-8 under 35 USC § 112, second paragraph set forth in section 23 of the previous Office action mailed June 4, 2002 (Paper No. 15) have been withdrawn for the following reason:

Even though the polynucleotide sequence of the DNA insert of ATCC Deposit No. PTA-1755 is not actually described in the specification, the DNA insert is defined at page 2, lines 26-29, to be a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. Therefore, it is clear that the polynucleotide sequence of the claimed DNA insert differs from SEQ ID NO: 4, but nevertheless the claimed DNA insert must necessarily encode the human SECS-1 polypeptide, i.e., SEQ ID NO: 5, since the specification discloses that a nucleic acid molecule encoding the human SECS-1 polypeptide was subcloned into a vector designated p7T73D and the resultant clone was deposited on April 25, 2000 as Deposit No. PTA-1755 (page 84, lines 15-19). Therefore, the deposit, once perfected according to the requirements set forth by the Budapest Treaty, will be deemed to suffice to describe the DNA insert to which the claims are drawn. The DNA insert of the claims is thus regarded as the portion of the cloned nucleic acid molecule in the deposit having ATCC Deposit No. PTA-1755, which encodes the human SECS-1 polypeptide, and which does not comprise a portion of the parental cloning vector, p7T73D.

Specification

9. The specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of improperly demarcated trademarks include DYNAL and DYNABEADS (page 85), Clontech™ (page 86), BIOSOURCE (page 86), AMBION (page 87), KODAK (page 88), QIAQUICK (page 88), Qiagen™ (pages 88 and 92),

READY TO GO (page 89), BIOGENEX (page 93), PHARMINGEN (page 93), and BIOTEK (page 93).

Appropriate corrections are required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

Claim Objections

10. Claims 3-8 are objected to because of the following informalities:

Claims 3-8 are objectionable because claim 3 is drawn in the alternative to the subject matter of non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 2 and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 recites, "but not more than 80 amino acid residues". In Paper No. 3, Applicants have remarked that support for the amendments can be found in the specification at, for example, page 2, page 3, page 22, and in Figure 3. However, the disclosures and the figure to which Applicants have referred do not appear to be proper and sufficient antecedent basis for recitation of this limitation in the claims. Accordingly,

the recitation of the limitation in the claim appears to introduce new matter and thereby violates the written description requirement of 35 USC § 112, first paragraph.

This issue might be resolved if Applicants were to point to specific disclosures in the specification that are believed to provide the necessary support.

13. The specification is objected to and claims 1, 2, and 4-8 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g., the disclosure of the claimed nucleic acid molecule's polynucleotide sequence); or (3) deposited.

Claims 1 and 2 are drawn to a nucleic acid comprising at least a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755. However, because the polynucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755 is not set forth in the specification, it is apparent that the DNA insert in ATCC Deposit No. PTA-1755 would be required to make and use the claimed invention. As a required element, the DNA insert in ATCC Deposit No. PTA-1755 must be known and readily available to the public, or otherwise obtainable by a repeatable method set forth in the specification. If it is not so available or obtainable, a deposit containing the claimed nucleic acid molecule may satisfy the enablement requirements of 35 USC 112, first paragraph. See 37 CFR §§ 1.801-1.809.

The referral to the deposit at page 84 of the specification is insufficient assurance that all required deposits have been made and all the conditions of MPEP 608.01 (p)(c) are met.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the

grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection/rejection.

14. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the claimed method to produce a polypeptide, or a fragment thereof, which comprises the amino acid sequence set forth in SEQ ID NO: 5, does not reasonably provide enablement for using the claimed method to produce any other polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 8 is drawn to a method for producing a polypeptide comprising culturing a host cell comprising a vector comprising a nucleic acid molecule of claim 1, 2, or 3.

The specification teaches that the polynucleotide sequence set forth in SEQ ID NO: 4 encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 5. Furthermore, the specification teaches that the DNA insert in ATCC Deposit No. PTA-1755 comprises a polynucleotide sequence encoding a human SECS-1 polypeptide, which is an allelic variant or splice variant of the polypeptide encoded by SEQ ID NO: 4.

The specification fails to provide an enabling disclosure of the claimed invention, as required by 35 USC § 112, first paragraph, since the amount of guidance, direction, and exemplification set forth therein are not reasonably commensurate in scope with the claims.

The claims encompass a method for producing a polypeptide that is encoded by a nucleic acid molecule comprising a polynucleotide sequence that is complementary to a polynucleotide sequence encoding SEQ ID NO: 5, or which is complementary to SEQ ID NO: 4. However, the specification does not describe any polypeptide encoded by a nucleic acid molecule comprising a polynucleotide sequence that is complementary to a polynucleotide sequence encoding SEQ ID NO: 5, or which is complementary to SEQ ID NO: 4. Furthermore, the host cell of claim 5 is expected to produce hundreds of polypeptides; yet the specification merely teaches that the host cell can be used to produce a polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

In addition, even should a polypeptide encoded by a nucleic acid molecule comprising a polynucleotide sequence that is complementary to a polynucleotide sequence encoding SEQ ID NO: 5, or which is complementary to SEQ ID NO: 4 be produced according to the claimed method, the polypeptide is not expected to have the same, or even a similar structure and function as does the polypeptide of SEQ ID NO: 5, and the specification does not provide any guidance, direction, or exemplification teachings how these polypeptides might be used.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 2, and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by the FAPESP/LICR Human Cancer Genome Project (GenBank EST Database Accession No. AW351839, 01 February 2000), as evidenced by a USPTO database search using SEQ ID NO: 5 as a query (see USPTO Search Report US-09-599-087-

5.rst, result 1), for the reasons stated in section 20 of the previous Office Action mailed June 4, 2002 (Paper No. 15).

This rejection has been set forth herein solely because claim 1 was inadvertently not included in the list of claims rejected under these grounds in the previous Office action. Claim 1 is drawn to a nucleic acid molecule comprising a nucleotide sequence that encodes a polypeptide as set forth in SEQ ID NO: 5, and the FAPESP/LICR Human Cancer Genome Project reference teaches the polynucleotide sequence of an isolated nucleic acid molecule, which encodes an amino acid sequence that is 100% identical to the amino acid sequence set forth in SEQ ID NO: 5.

Nevertheless, this rejection has been overcome by the declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy for the reasons set forth above.

17. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier, et al (GenBank EST Database Accession No. AA422178, 1997), as evidenced by a USPTO database search using SEQ ID NO: 5 as a query (see USPTO Search Report US-09-599-087-5.rst, result 2).

Hillier, et al teach the polynucleotide sequence of an isolated nucleic acid molecule encoding an amino acid sequence that is 100% identical to the amino acid sequence set forth in SEQ ID NO: 5 over the region spanning from the amino acid at position 1 to the amino acid at position 76. According to the annotation of GENBANK Accession No. AA422178, the polynucleotide sequence of the complementary DNA (cDNA) molecule of Hillier, et al is contained in a modified vector originally designated pT7T3D. The recombinant vector comprising the polynucleotide sequence of the cDNA molecule was cloned in a host prokaryotic cell designated DH10B.

The nucleic acid molecule of Hillier, et al does not comprise the nucleotide sequence set forth in SEQ ID NO: 4; nor does the nucleic acid molecule of Hillier, et al comprise a nucleotide sequence encoding a polypeptide having the amino acid sequence set forth in SEQ ID NO: 5. Nevertheless, the nucleic acid molecule of Hillier, et al does comprise a polynucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 4, since the nucleic acid molecule of Hillier, et al comprises

the polynucleotide sequence set forth between nucleotide residues 1 and 60, which is complementary to the polynucleotide sequence of SEQ ID NO: 4. Therefore, Hillier, et al anticipates the invention of claim 1, which in this instance is interpreted as an isolated nucleic acid molecule *comprising* a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 4.

Additionally, although Hillier, et al do not teach that the nucleic acid molecule comprises the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755, the specification does not teach the actual polynucleotide sequence of the DNA insert. The specification discloses only that the DNA insert encodes a human SECS-1 polypeptide and has a polynucleotide sequence that differs from SEQ ID NO: 4 since, according to the disclosure at page 2, lines 26-29, the DNA insert comprises the polynucleotide sequence of an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. The nucleic acid molecule of Hillier, et al has a polynucleotide sequence that differs from SEQ ID NO: 4, but which encodes an amino acid sequence that is 100% identical to the amino acid sequence set forth in SEQ ID NO: 5 over the region spanning from the amino acid at position 1 to the amino acid at position 76. Therefore, absent a showing of any difference, the nucleic acid molecule of Hillier, et al is deemed the same as the claimed nucleic acid molecule comprising the nucleotide sequence of the DNA insert in the ATCC Deposit No. PTA-1755, which necessarily encodes a variant of the polypeptide encoded by SEQ ID NO: 4. The Office, however, does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed product is different than that taught by the prior art.

With regard to claim 2, the nucleic acid molecule of Hillier, et al is deemed to *comprise* a region of the nucleotide sequence of both SEQ ID NO: 4 and, absent a showing of any difference, the DNA insert in ATCC Deposit No. PTA-1755, which encode a polypeptide of at least 25 amino acids, but not more than 80 amino acids, which upon injection into an animal would produce an antibody that binds to the

polypeptide of SEQ ID NO: 5. Again, the Office does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as the claimed product. Nevertheless, the nucleic acid molecule of Hillier, et al comprises, for example, the region of the polynucleotide sequence of SEQ ID NO: 4 spanning nucleotide residues 29 to 130, which encodes amino acids 1-34 of SEQ ID NO: 5. This region of the nucleic acid molecule of Hillier, et al is deemed anticipatory of the invention of claim 2, absent a showing of any difference, because the region appears to encode a polypeptide of at least 25 amino acids, but not more than 80 amino acids, which upon injection into an animal would produce an antibody that binds to the polypeptide of SEQ ID NO: 5.

As for claim 3, claim 3 is only considered insofar as the claim is drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5, or comprising a nucleotide sequence that is complementary the nucleotide sequence encoding the polypeptide. Although the nucleic acid molecule of Hillier, et al does not comprise a nucleotide sequence encoding a polypeptide having the amino acid sequence set forth in SEQ ID NO: 5, the nucleic acid molecule of Hillier, et al does comprise a polynucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 4 encoding the polypeptide of SEQ ID NO: 5. For example, the nucleic acid molecule of Hillier, et al comprises the polynucleotide sequence set forth between nucleotide residues 1 and 60, which is complementary to the polynucleotide sequence of SEQ ID NO: 4, or which is complementary to a nucleotide sequence encoding the polypeptide of SEQ ID NO: 5. Therefore, Hillier, et al anticipates the invention of claim 3.

Applicants have traversed this ground of rejection. Applicants have argued that the open reading frame of the polynucleotide sequence of the isolated cDNA molecule of Hillier, et al encodes a polypeptide having an amino acid sequence that is 98 residues in length, and because claim 2 recites the limitation, "but not more than 80 amino acid residues", the prior art does not anticipate the claimed invention. Applicants

have also argued that the polypeptide encoded by the nucleic acid molecule of Hillier, et al comprises the amino acid sequence Glu-Ser-His-Arg-Cys at positions 77-81, and because claim 3 requires polypeptide encoded by the claimed nucleic acid molecule to have the amino acid sequence Ala-Leu-Pro-Glu-(Iso/Val) at positions 77-81, the prior art does not anticipate the claimed invention.

Applicants' arguments have been carefully considered but not found persuasive for the following reasons:

Claim 2 is interpreted to be drawn to a nucleic acid molecule *comprising a region* of the nucleotide sequence set forth in SEQ ID NO: 4 that encodes a polypeptide of at least 25, but not more than 80 amino acids, which when used as an immunogen would produce an antibody that binds the polypeptide of SEQ ID NO: 5. As explained above, the nucleic acid molecule of Hillier, et al is deemed to *comprise* a region of the nucleotide sequence of both SEQ ID NO: 4 and, absent a showing of any difference, the DNA insert in ATCC Deposit No. PTA-1755, which encode a polypeptide of at least 25 amino acids, but not more than 80 amino acids, which upon injection into an animal would produce an antibody that binds to the polypeptide of SEQ ID NO: 5. This region of the nucleic acid molecule of Hillier, et al is deemed anticipatory of the invention of claim 2, absent a showing of any difference, because the region appears to encode a polypeptide of at least 25 amino acids, but not more than 80 amino acids, which upon injection into an animal would produce an antibody that binds to the polypeptide of SEQ ID NO: 5. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed product is different than that taught by the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA, 1977) and *Ex parte Gray*, 10 USPQ2d 1922 1923 (PTO Board of Patent Appeals and Interferences, 1988 and 1989).

Presently claim 3 is drawn to a nucleic acid molecule *comprising* a nucleotide sequence that is complementary to a nucleotide sequence encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5. As explained above, the nucleic acid molecule of Hillier, et al comprises a polynucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 4 encoding the polypeptide of SEQ ID NO: 5, and an example has been given. Therefore, although the nucleotide

sequence of Hillier, et al does not encode a polypeptide having the amino acid sequence Ala-Leu-Pro-Glu-(Iso/Val) at positions 77-81, Hillier, et al anticipates the invention of claim 3.

18. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Database GENBANK Accession No. AA283751, as evidenced by the declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed September 25, 2002 as part of Paper No. 18, Hillier, et al (*Genome Research* **6**: 807-828, 1996), Exhibit A (a printout of Internet accessible information regarding GENBANK Accession No. AA283751), and Exhibit B (an email communication from Christa Prange of the IMAGE Consortium dated May 12, 2003 in reply to the Examiner's query made May 7, 2003).

GENBANK Accession No. AA283751 teaches an isolated complementary DNA (cDNA) molecule, which, as evidenced by Exhibit A, was cloned into a modified vector originally designated pT7T3D and is contained in an isolated prokaryotic host cell designated DH10B. This clone is available royalty-free through the IMAGE Consortium. As evidenced by Exhibit B, an email communication from Christa Prange of the IMAGE Consortium, by April or May of 1997, the clone was made publicly available through the clone distributors. Hillier, et al describe the methods by which the isolation and procurement of the cDNA was accomplished.

Although the polynucleotide sequence of the isolated cDNA molecule of the prior art is reported as being different from the polynucleotide sequence set forth in SEQ ID NO: 4, the declaration by Anthony J. Polverino and Roland Luethy filed September 25, 2002 as part of Paper No. 18 provides evidence that the cDNA of the prior art is the same as the claimed nucleic acid molecule. The declaration states: (a) the amino acid sequence of an isolated polypeptide was determined by Applicants, (b) the determined amino acid sequence was used by Applicants as query in searching the databases to identify expressed sequence tags (ESTs) that are capable of encoding the isolated polypeptide, (c) GENBANK Accession No. AA283751 was identified by Applicants as containing sequences capable of encoding the polypeptide, (d) a clone containing the nucleotide sequence purportedly disclosed as GENBANK Accession No. AA283751

was acquired by Applicants from the IMAGE Consortium, and (e) the polynucleotide sequence of the cDNA insert of the acquired clone was determined by Applicants. The declaration further states the polynucleotide sequence of the cDNA insert of the acquired clone is depicted in thereto attached Exhibit B; the declaration also states that the polynucleotide sequence depicted in Exhibit B is the same as the polynucleotide sequence set forth as SEQ ID NO: 4 in the application. Accordingly, the cDNA of the prior art is the same as the claimed nucleic acid molecule.

Although the polynucleotide sequence of the cDNA molecule of the prior art is, according to Applicants' declaration, different from the polynucleotide of the claimed nucleic acid molecule, the polynucleotide sequence of a nucleic acid molecule is an inherent property. The claims are drawn to a nucleic acid molecule having the same polynucleotide sequence as the nucleic acid molecule of the prior art, as evidenced by Applicants' declaration.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over The FAPESP/LICR Human Cancer Genome Project (GenBank EST Database Accession No. AW351839, 01 February 2000), as evidenced by a USPTO database search using SEQ ID NO: 5 as a query (see USPTO Search Report US-09-599-087-5.rst, result 1), for the reasons stated in section 20 of the previous Office Action mailed June 4, 2002 (Paper No. 15).

This rejection has been set forth herein solely because claim 1 was inadvertently not included in the list of claims rejected under these grounds in the previous Office action. Claim 1 is drawn to a nucleic acid molecule comprising a nucleotide sequence

that encodes a polypeptide as set forth in SEQ ID NO: 5, and the FAPESP/LICR Human Cancer Genome Project reference teaches the polynucleotide sequence of an isolated nucleic acid molecule, which encodes an amino acid sequence that is 100% identical to the amino acid sequence set forth in SEQ ID NO: 5.

Nevertheless, this rejection has been overcome by the declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy for the reasons set forth above.

21. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier, et al (GenBank EST Database Accession No. AA422178, 1997), as evidenced by a USPTO database search using SEQ ID NO: 5 as a query (see USPTO Search Report US-09-599-087-5.rst, result 2), in view of Bendig (*Genet Eng* **7**: 91-127, 1988) and Niwa, et al (*Gene* **108**: 193-199, 1991).

Hillier, et al teach that which is set forth in the rejection of claims 1, 2, 3-5, and 7 under 35 USC § 102(b) above. Additionally, Hillier, et al teach the cDNA molecule was isolated from human ovarian tumor tissue.

However, Hillier, et al do not disclose a eukaryotic host cell; nor does Hillier, et al disclose a process for producing the polypeptide encoded by the polynucleotide sequence of the isolated cDNA molecule.

Nevertheless, Bendig and Niwa, et al teach the production of recombinant proteins in mammalian cells using eukaryotic expression vectors. Additionally, Bendig teaches that mammalian host cells are capable of post-translational processing and secretion, processes of which prokaryotic cells are incapable.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make and use an eukaryotic expression vector comprising the nucleic acid molecule of Hillier, et al so that the polypeptide encoded thereby could be produced in mammalian cells. Methods for construction of expression vectors, methods for introduction of expression vectors into eukaryotic and prokaryotic host cells, and methods for production of polypeptides encoded by expression vectors were conventional at the time the invention was made, as evidenced by the teachings of Bendig and Niwa, et al. One of ordinary skill in the art at the time the invention was

made would have been motivated to make and use a eukaryotic expression vector comprising the nucleic acid molecule of Hillier, et al so as to produce the polypeptide encoded thereby in mammalian cells, because the polypeptide produced by a eukaryotic host cell would be post-translationally processed or secreted, as the naturally produced polypeptide would be.

Applicants have traversed this ground of rejection by referring to the arguments set forth in traversing the corresponding rejection under 35 USC §102. In addition, Applicants have traversed this ground of rejection of claim 8 arguing that the polynucleotide sequence of Hillier, et al does not encode a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5. Furthermore, Applicants have argued that the polypeptide encoded by the nucleic acid molecule of Hillier, et al would be more than 80 amino acids in length and would not have the amino acid sequence Ala-Leu-Pro-Glu-(Iso/Val) at positions 77-81. Therefore, Applicants have contended even given the teachings of Hillier, et al, the invention would not have been obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' arguments have been carefully considered but not found persuasive for the reasons already given in response to those arguments. Furthermore, with regard to the instant rejection of claim 8, Applicants' argument relies upon limitations that are not recited in the claim. Claim 8 does not presently recite a limitation requiring the polypeptide produced to comprise the amino acid sequence of SEQ ID NO: 5, nor does the claim require the polypeptide produced to be a fragment of SEQ ID NO: 5 consisting of at least 25, but not more than 80 amino acid residues. To the contrary, the presently claim 8 is drawn to a method for producing a polypeptide comprising culturing a host cell comprising a vector comprising the nucleic acid molecule of claims 1, 2, or 3. The nucleic acid molecule of claims 1, 2, and 3 is not limited to a nucleic acid molecule encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, nor is the nucleic acid molecule of claims 1, 2, and 3 limited to a nucleic acid molecule encoding a polypeptide fragment of SEQ ID NO: 5 consisting of at least 25, but not more than 80 amino acid residues. Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed Cir, 1993).

22. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Database GENBANK Accession No. AA283751, as evidenced by the declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed September 25, 2002 as part of Paper No. 18, Hillier, et al (*Genome Research* **6**: 807-828, 1996), Exhibit A (a printout of Internet accessible information regarding GENBANK Accession No. AA283751), and Exhibit B (an email communication from Christa Prange of the IMAGE Consortium dated May 12, 2003 in reply to the Examiner's query made May 7, 2003) in view of Bendig (*Genet Eng* **7**: 91-127, 1988) and Niwa, et al (*Gene* **108**: 193-199, 1991).

Database GENBANK Accession No. AA283751 teach that which is set forth in the rejection of claims 1, 2, 3-5, and 7 under 35 USC § 102(b) above. Additionally, the annotation of GENBANK Accession No. AA283751 teach the cDNA molecule was isolated from human ovarian tumor tissue.

However, the annotation of GENBANK Accession No. AA283751 does not disclose a eukaryotic host cell; nor does the annotation disclose a process for producing the polypeptide encoded by the polynucleotide sequence of the isolated cDNA molecule.

Nevertheless, Bendig and Niwa, et al teach the production of recombinant proteins in mammalian cells using eukaryotic expression vectors. Additionally, Bendig teaches that mammalian host cells are capable of post-translational processing and secretion, processes of which prokaryotic cells are incapable.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make and use an eukaryotic expression vector comprising the nucleic acid molecule of Hillier, et al so that the polypeptide encoded thereby could be produced in mammalian cells. Methods for construction of expression vectors, methods for introduction of expression vectors into eukaryotic and prokaryotic host cells, and methods for production of polypeptides encoded by expression vectors

were conventional at the time the invention was made, as evidenced by the teachings of Bendig and Niwa, et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make and use a eukaryotic expression vector comprising the nucleic acid molecule of Hillier, et al so as to produce the polypeptide encoded thereby in mammalian cells, because the polypeptide produced by a eukaryotic host cell would be post-translationally processed or secreted, as the naturally produced polypeptide would be.

Conclusion

23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

slr
May 13, 2003